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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,847

12/05/2003

William Alston

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10/11/2006

NEKTAR THERAPEUTICS  
150 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT

PAPER NUMBER

3771

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/729,847

Applicant(s)

ALSTON, WILLIAM

Examiner

Shumaya B. Ali

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

DETAILED ACTION

*Response to Arguments*

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection. Claims 1-20 are pending in the current application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As to claims 4 and 14, meets and bounds of claimed limitation cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-7, 10-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. US Patent No. 4,249,526**

**As to claim 1,** Dean et al discloses an aerosolization apparatus comprising: a body (fig.1, 1) defining an inlet opening (fig.1, 11/12), an outlet opening (toward the mouthpiece, fig.1, 5), and an aerosolization chamber (fig.2, 15) between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle (fig.2, 24) containing a pharmaceutical formulation (col.2 lines 1-8) and wherein the elongated receptacle rotates, an axis end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body (2-fold axis of symmetry reads on end-over-end, see col.4 lines 32-38, figs.3 and 4).

**As to claim 2,** Dean et al. discloses an aerosolization apparatus according to claim 1 further comprising an opening mechanism (see fig.1, 20) for creating an opening in the receptacle.

**As to claim 3,** Dean et al. discloses an aerosolization apparatus according to claim 2 wherein the opening mechanism comprises a sharpened tip (pins with sharp tips as depicted in fig.1, 20) moveable within the aerosolization chamber (col.4 lines 15-35).

**As to claim 4,** Dean et al. discloses an aerosolization apparatus according to claim 1 further comprising the receptacle (see fig.2)

**As to claim 5**, Dean et al. discloses an aerosolization apparatus according to claim 4 wherein the receptacle comprises a capsule (fig.2, 24).

**As to claim 6**, Dean et al. disclose an aerosolization apparatus according to claim 5 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar (col.2 lines 1-8).

**As to claim 7**, Dean et al. discloses an aerosolization apparatus according to claim 5 wherein the receptacle contains a powder pharmaceutical formulation (col.1 lines 25-29).

**As to claim 10**, Dean et al. discloses an aerosolization apparatus for delivering an aerosolized pharmaceutical formulation to a user's respiratory tract, the apparatus comprising: a body (fig.1, 1) defining an inlet opening (fig.1, 11), an outlet opening (toward the mouthpiece, fig.1, 5), and an aerosolization chamber (see fig.2, 15) between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle (see fig.2, 24) containing a pharmaceutical formulation (col.2 lines 1-8), an axis (parallel to a longitudinal axis of the apparatus), wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body (2-fold axis of symmetry reads on end-over-end, see col.4 lines 32-38, figs.3 and 4).

**As to claim 11**, Dean et al. discloses an aerosolization apparatus according to claim 10 wherein the inhalation direction is a direction coincident with an axis passing through a mouthpiece (fig.1, 3) of the apparatus.

**As to claim 12**, Dean et al. discloses an aerosolization apparatus according to claim 10 further comprising an opening mechanism (see fig.1, 20) for creating an opening in the receptacle.

**As to claim 13**, Dean et al. discloses an aerosolization apparatus according to claim 12 wherein the opening mechanism comprises a sharpened tip (pins with sharp tips as depicted in fig.1, 20) moveable within the aerosolization chamber (col.4 lines 15-35).

**As to claim 14**, Dean et al. discloses an aerosolization apparatus according to claim 10 further comprising the receptacle (see fig.2)

**As to claim 15**, Dean et al. disclose an aerosolization apparatus according to claim 14 wherein the receptacle comprises a capsule (col.2 lines 1-7).

**As to claim 16**, Dean et al. disclose an aerosolization apparatus according to claim 15 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar (col.2 lines 1-8).

**As to claim 17**, Dean et al. disclose an aerosolization apparatus according to claim 15 wherein the receptacle contains a powder pharmaceutical formulation (col.1 lines 25-29).

As to claim 20, Dean et al. disclose an aerosolization apparatus according to claim 10 wherein the inlet opening is shaped to cause a swirling air or gas flow through the chamber (col.4 lines 30-38).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. US Patent No. 4,249,526.**

As to claim 8, Dean et al. does not disclose an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 um. A close review of the applicant's disclosure reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 14, lines 26-27). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication. Therefore, the Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of tissue, and tissue can vary from patient to patients. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to manipulate the mass median diameter of pharmaceutical formulation particles because doing so would have allowed treatment depending on patient's tissue absorbent efficiency.

As to claim 18, Dean et al. discloses claimed invention as applied to claim 8.

**Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. US Patent No. 4,249,526 and in view of Chiprich et al. US Patent 5,614,217**

As to claim 9, Dean et al. does not disclose an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation has moisture content below 5% by weight. A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in



the prior art (see specification page 15, lines 2-4). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established why a moisture content of 10% or 3% by weight would be critical to the invention. Chiprich et al. in a capsule shell formulation teach a brittle gelatin capsule comprises about 5-15% water by weight to provide a finished capsule which remains breakable with manual pressure in changing environmental conditions without the need of special treatments or moisture resistant packaging (col.1 lines 55-60 and col.2 lines 51-55). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Dean et al. in view of Chiprich in order to provide a moisture content of 5-15% because doing so would have allowed breakable of capsule with manual pressure in changing environmental conditions without the need of special treatments or moisture resistant packaging.


**As to claim 19,** Dean et al. disclose claimed invention as applied to claim 9.

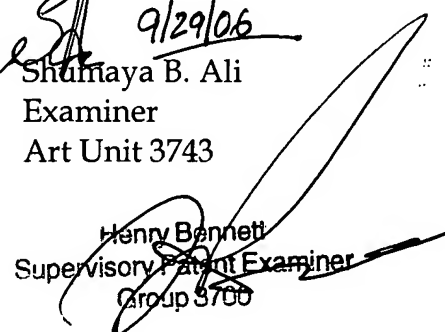
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-F 8:30-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 9/29/06  
Shumaya B. Ali  
Examiner  
Art Unit 3743

  
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